IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,)
Plaintiff,)) Case No. 16-CV-129-JED-JFJ
v.)
DARNELL E. BLACKMON, M.D.,)
Defendant.)

OPINION AND ORDER

I. Background

Plaintiff, the United States of America, on behalf of the Drug Enforcement Agency (DEA), brought this suit against defendant, Darnell E. Blackmon, M.D., under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. (the Act). Dr. Blackmon is a Board-certified orthopedic surgeon, who served as the Medical Director for the Enhanced Skin & Body Medical Spa (the Spa) beginning June 9, 2011. In its Complaint, the government alleged that, while he was the Spa's Medical Director, Dr. Blackmon committed multiple violations of the Act and related regulations. (*See* Complaint, Doc. 2).

Dr. Blackmon has admitted several of the violations, as set forth in Stipulations (Doc. 47) filed with the Court. Among other stipulations, the parties agreed that the only issues remaining were the amounts of civil monetary penalties to be levied against Dr. Blackmon for the stipulated violations, and they agreed that the Court should make those determinations in a non-jury trial. (*See id.*). Thus, on October 26, 2017, the Court conducted a non-jury trial regarding the appropriate monetary penalties. At trial, the Court heard the testimony of four witnesses, who were called by the plaintiff: Kimberly Daniels, a Group Supervisor with the DEA; Robbin Roberts,

Investigator with the Oklahoma Medical Board; Dr. Blackmon, the defendant; and Elisa Kaye Sanders, RN, who was an owner of the Spa. The Court admitted Plaintiff's Exhibits (PX) 1 through 21 and Defendant's Exhibits (DX) 1 through 3. Upon consideration of the Stipulations (Doc. 47), all testimony, exhibits, trial briefs (Doc. 53, 54), and the parties' proposed findings of fact and conclusions of law (Doc. 48, 49), the Court enters the following findings and conclusions. ¹

II. Findings of Fact

Dr. Blackmon has stipulated liability to Counts I, II, III, IV, VI, VII, and VIII of the Complaint, and the Court incorporates those Stipulations (Doc. 47) herein as findings of fact. Each Count is described below, along with the maximum statutory penalty, and the amounts the government requests that the Court impose.

Count I: Dr. Blackmon failed to record at the Spa an initial inventory for phentermine and testosterone, in violation of 21 U.S.C. §§ 827(a)(1), 842(a)(5) and 21 C.F.R. § 1304.11(b), which subjects him to a maximum monetary penalty of not more than \$10,000 pursuant to 21 U.S.C. § 842(c)(1)(B). The government requests that the Court order that Dr. Blackmon pay a civil penalty of \$1,000 on this Count.

Count II: Dr. Blackmon failed to maintain at the Spa a biennial inventory for testosterone and phentermine, in violation of 21 U.S.C. §§ 827(a)(1), 842(a)(5) and 21 C.F.R. § 1304.11(c), which subjects him to a maximum monetary penalty of not more than \$10,000 pursuant to 21 U.S.C. § 842(c)(1)(B). The government requests that the Court impose a \$1,000 penalty on this Count.

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Any findings of fact that are conclusions of law shall be construed accordingly, and any conclusions of law that are findings of fact shall be construed accordingly.

Count III: Dr. Blackmon failed to maintain at the Spa a dispensing log for testosterone and phentermine, in violation of 21 U.S.C. §§ 827(a)(3), 842(a)(5) and 21 C.F.R. § 1304.03(b), subjecting him to a maximum monetary penalty of not more than \$10,000, pursuant to 21 U.S.C. § 842(c)(1)(B). The government requests that the Court impose a \$1,000 penalty on this Count.

Count IV: On 55 occasions, the dates testosterone and phentermine were received at the Spa were not recorded, subjecting Dr. Blackmon to a maximum monetary penalty of not more than \$10,000 for each of the 55 occasions, pursuant to 21 U.S.C. § 842(a)(5), (c)(1)(B). The government requests that the Court order that Dr. Blackmon pay a penalty of \$1,000 for each of the 55 violations under this Count, for a total of \$55,000.

Count V: The parties stipulate that Count V shall be dismissed with prejudice.

Count VI: On 368 occasions, in violation of 21 U.S.C. §§ 829(b) and 842(a)(1) and 21 C.F.R. §§ 1306.04 and 1306.05, Dr. Blackmon permitted Pam Kirkendall and Elisa Kaye Sanders, both of whom were RNs, to examine patients, determine the type and course of treatment, prescribe and/or administer testosterone and/or phentermine, in Dr. Blackmon's absence and without the presence of another licensed physician, outside the course of his professional practice and without him establishing a doctor-patient relationship. He is subject to a maximum monetary penalty of not more than \$25,000 for each of the 368 violations, for a total maximum of \$9,200,000. The government requests that the Court impose a penalty of \$1,000 for each of the 368 violations, for a total of \$368,000.

Count VII: In violation of 21 U.S.C. §§ 829(b) and 842(a)(1) and 21 C.F.R. §§ 1306.04 and 1306.05(f), Dr. Blackmon prescribed and was administered testosterone on three occasions, without a prescription from another DEA-registered physician with whom he had established a doctor-patient relationship. Each of those violations subjects him to a maximum monetary penalty

of not more than \$25,000. The government requests that the Court impose a penalty amounting to \$1,000 per violation, for a total of \$3,000, under this Count.

Count VIII: Dr. Blackmon failed to obtain a separate DEA registration for dispensing activities at the Spa, in violation of 21 U.S.C. §§ 822(e)(1) and 842(a)(2) and 21 C.F.R. § 1301.12(a), subjecting him to a maximum monetary penalty of \$25,000. The government requests the imposition of a civil penalty of \$12,500 for Dr. Blackmon's failure to obtain a separate DEA registration for his dispensing activities at the Spa.

In addition to the stipulated facts, based upon the testimony and demeanor of the witnesses, and the exhibits admitted into evidence, the Court makes the following additional findings. By agreement dated June 9, 2011, Dr. Blackmon agreed to serve as the Medical Director of the Spa. (PX 2). Pursuant to the agreement, such services included "provid[ing] professional medical direction relating to the medical services," providing "administrative services," being "available for consultation relating to medical spa services," and providing medical director services "in such a manner as may be required by any standard, ruling or regulation of the State, Department of Health or any other applicable federal, state or local agency exercising authority with respect to [the Spa]." (*Id.*).

In consideration of his Medical Director services, the Spa agreed to pay Dr. Blackmon \$500 monthly. (*Id.*). Testimony also reflected that Dr. Blackmon invested \$25,000 in the Spa, but he was not paid a return on the investment. He was paid only the \$500 monthly fee under the agreement, and was not paid any additional amounts that related to number of patients who received the testosterone or phentermine treatments.

There was inconsistent testimony at trial with regard to when Dr. Blackmon became aware that the Spa would begin providing services that included testosterone and phentermine. Dr.

Blackmon testified that he did not learn that the Spa intended to provide phentermine and testosterone treatments until after the Spa had been providing such treatments. Dr. Blackmon also testified that, while Spa personnel utilized a stamp of his signature and his DEA number to order testosterone and phentermine, he did not authorize the making of the stamp or its use for testosterone and phentermine, at least at the time when those controlled substances were integrated into the Spa's treatment services. In contrast, Sanders testified that it was Dr. Blackmon who initiated a contact from a pharmaceutical representative from Testopel – who was Dr. Blackmon's neighbor – for the purpose of considering the addition of testosterone treatments at the Spa. Sanders also testified that she had discussions directly with Dr. Blackmon about the meeting with Testopel and that he encouraged her to move forward with offering hormone replacement therapy.

Considering the conflicting testimony and the demeanor and motivations of the witnesses, the Court finds Sanders to be more credible on this issue. Among other things, Dr. Blackmon was impeached with his prior statements regarding the signature stamp. His testimony at trial – that he did not initially authorize the signature stamp for use by the Spa – was inconsistent with his prior testimony that he gave his signature to Sanders to obtain a signature stamp. His attempts to deflect responsibility for the stamp onto the Spa were apparent given the multiple inconsistencies in his statements regarding the origination of the stamp and his allegations that he lacked knowledge with respect to the stamp. For example, when initially questioned by investigators, Dr. Blackmon asserted that "he was not aware of whether the Spa staff possessed a stamp of his signature." (PX 20 at ¶ 11). On cross-examination by his counsel at trial, he attempted to clear up the multiple versions of his claims about the stamp, but the Court did not consider his explanations to be credible in light of the inconsistencies. Sanders testified that it was Dr. Blackmon who provided the signature stamp to the Spa, which the Court considered to be credible testimony.

Testosterone is a Schedule III controlled substance, and phentermine is a Schedule IV controlled substance. According to Dr. Blackmon, he was not aware that testosterone or phentermine were controlled substances. However, according to testimony at trial, Dr. Blackmon could easily have located information regarding DEA registration requirements, drug names and schedules, information on how to contact local and national DEA officials, and a practitioners' guide regarding controlled substances, all of which are available on DEA's website. Dr. Blackmon also admitted that he researched testosterone when he first became aware of its use at the Spa, and he was contractually responsible for complying with legal requirements under his Medical Director agreement with the Spa.

There was no evidence of any specific adverse outcome with respect to any Spa patient who was administered phentermine or testosterone. However, the government presented evidence that the investigation into the Spa's use of controlled substances was initiated due to a complaint by a patient who was concerned that she was never seen by a physician in connection with hormone replacement treatment. Dr. Blackmon also admitted that potential side effects of testosterone pellet insertion include infection, extrusion of the pellet, rise in red blood cell count, tumor growth enhancement in patients with prostate cancer, and a decrease in sperm count. He was also aware that phentermine use carried risks of hyperactivity, headache, dizziness, and sleep problems.

Neither Dr. Blackmon nor Kaye Sanders were aware that a separate DEA registration was required for the Spa or that special recordkeeping requirements existed with respect to phentermine and testosterone. According to Sanders, phentermine and testosterone were recorded in client charts, although separate dispensation logs were not maintained at the Spa. The evidence did not show that either testosterone or phentermine were diverted for sale to any persons other than the patients who received those controlled substances at the Spa. DEA testimony at trial indicated that

the DEA was prevented from fully determining whether any controlled substances were diverted, because of the absence of required recordkeeping.

Dr. Blackmon has worked as an orthopedic surgeon since 2003. With respect to a short period of time when he was in Afghanistan and his 20-day suspension from his medical practice, he has continuously been employed during those 14 years, and he is in practice today. He previously paid two fines in connection with investigation of his involvement in the Spa's medical procedures. One fine was \$50,000 paid to the Oklahoma Medical Board, and another was \$12,000 paid to the Oklahoma Bureau of Narcotics. In opening statements, Dr. Blackmon's counsel asserted that Dr. Blackmon's practice had suffered because he had lost insurance payers because he is subject to supervision by the Board of Medical Licensure for five years. The defense also offered, and the Court admitted, DX 3, which consists of letters from five insurance companies indicating that Dr. Blackmon's participation in those companies' provider networks was terminated. (*See* DX 3). However, Dr. Blackmon did not testify regarding any particular economic impact of those letters, nor did he testify that his income or assets were rendered insufficient to enable him to pay monetary penalties. Other than the foregoing, no evidence was presented at trial regarding Dr. Blackmon's ability, or inability, to pay any monetary penalty.

As will be explained further below in the context of applicable legal standards, the Court finds that a significant monetary penalty is appropriate with respect to the hundreds of violations of the Act to which Dr. Blackmon has stipulated.

III. Conclusions of Law

The parties have stipulated, and this Court concludes, that the Court has jurisdiction under 28 U.S.C. §§ 1345 and 1355(a). In addition, venue is proper under 28 U.S.C. § 1395(a).

Pursuant to the Act, it is "unlawful for any person . . . to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required [under the Act]." 21 U.S.C. § 842(a)(5). Dr. Blackmon's violations of that provision, as stipulated under Counts I through IV, subject him to a maximum civil penalty of \$10,000 for each violation. *See* 21 U.S.C. § 842(c)(1)(B). As stipulated under Counts VI and VII, Dr. Blackmon violated 21 U.S.C. §§ 829(b) and 842(a)(1), and each of those violations carries a civil penalty of not more than \$25,000, pursuant to § 842(c)(1)(A). Dr. Blackmon's violation of 21 U.S.C. §§ 822(e)(1) and 842(a)(2), under Count VIII, subjects him to a penalty of not more than \$25,000 pursuant to 21 U.S.C. § 842(c)(1)(A).

At trial, the parties agreed upon factors typically considered by courts when considering the amount of civil monetary penalties for violations of the Act. The Second Circuit has provided guidance with respect to a district court's exercise of discretion in determining the amount of civil monetary penalty to impose under the Act. *See Advance Pharmaceutical, Inc. v. United States*, 391 F.3d 377, 399 (2d Cir. 2004). "A district court may properly consider 'a number of factors' in determining the size of a civil penalty, 'including the good or bad faith of the defendants, the injury to the public, and the defendants' ability to pay." *Id.* at 399 (quoting *United States v. J.B. Williams Co.*, 498 F.2d 414, 438 (2d Cir. 1974)). In *Advance Pharmaceutical*, the court noted that "district courts have frequently considered four factors: (1) the level of defendant's culpability, (2) the public harm caused by the violations, (3) defendant's profits from the violations, and (4) the

defendant's ability to pay a penalty." *Id.*; see also United States v. Poulin, 926 F. Supp. 246, 253-54 (D. Mass. 1996).

As noted, the violations to which Dr. Blackmon has stipulated expose him to a total maximum monetary penalty of \$9,880,000 for all counts combined. The government requests that the Court impose a total of \$441,500. Upon examination of the evidence and the factors which may be properly considered in determining the amount of penalties, the Court finds and concludes that Dr. Blackmon should pay the following penalties, totaling \$296,000: (1) \$250 as to each of the 58 violations under Counts I through IV, for a total of \$14,500 on those counts; (2) \$750 as to each of the 368 violations under Count VI, for a total penalty of \$276,000; (3) \$1,000 as to each of the three violations under Count VII, for a total of \$3,000 on that count; and (4) \$2,500 as to his failure to obtain a separate DEA registration for dispensing activities at the Spa, under Count VIII. The bulk of the total is derived from the 368 violations under Count VI, each carrying a maximum penalty of \$25,000. The Court's imposition of \$276,000 on that Count amounts to a penalty equal to only three percent (3%) of the \$9,200,000 maximum penalty to which Dr. Blackmon is subject under Count VI.

The Court considers the foregoing amounts, and the total combined, to be appropriate in light of Dr. Blackmon's culpability, which is the first factor typically considered. The Court's determinations regarding culpability include consideration of the very significant number of violations to which Dr. Blackmon has stipulated, the fact that Dr. Blackmon authorized the Spa to utilize his DEA registration to obtain controlled substances, which were prescribed and/or administered to patients of the Spa without Dr. Blackmon establishing any doctor-patient relationship, being present, or determining and complying with applicable laws concerning DEA registration, record-keeping, and prescription / administration of those controlled substances. He

also provided the Spa with a rubber stamp of his signature, as well as his DEA registration, to order controlled substances from out-of-state pharmacies.

In addition, Blackmon knowingly undertook responsibility for providing medical director services "in such a manner as may be required by any standard, ruling or regulation of the State, Department of Health or any other applicable federal, state or local agency exercising authority with respect to [the Spa]." (PX 2). Both legally and contractually, Dr. Blackmon was responsible for compliance with federal law. Yet, as he has stipulated, he committed 430 violations of the Act, which included improper prescription and/or administration of controlled substances on 368 occasions and three instances which involved Blackmon himself unlawfully receiving a Schedule III controlled substance. Dr. Blackmon urges that the Court should find his culpability to be low because of his assertion that he was unaware that testosterone and phentermine were controlled substances. However, his testimony established that he became aware that the spa was providing testosterone pellet insertions, and he conducted some research regarding testosterone at that time, but he did nothing to ensure that he and the Spa complied with the Act going forward. The Court also found Dr. Blackmon lacking in credibility in certain respects, and in particular, in relation to his testimony that (1) he was unaware that the Spa was offering testosterone treatments and (2) he did not provide his signature for a stamp or did not provide the stamp to the Spa.

In relation to the second factor, there was no evidence presented at trial that established any significant adverse outcome to the public from the Spa's services relating to testosterone and phentermine. While there was no evidence of any specific or significant adverse effects, Dr. Blackmon was aware of several potential side effects of the controlled substances, and the investigation was initiated upon a complaint of a patient concerned about the absence of physician oversight. In addition, testimony at trial established that the DEA was unable to determine whether

there was any diversion, because of Dr. Blackmon's failure to comply with the record-keeping requirements of the Act.

There was no evidence at trial that indicated the third factor – profitability – is a significant consideration in this case, because Dr. Blackmon did not directly profit from the Spa's testosterone and phentermine services. However, testimony at trial established that Sanders discussed profitability with Blackmon, he encouraged the Spa to offer the testosterone services, and it was through his acquaintance with the Testopel representative that the first contact was made with the Spa concerning testosterone treatments. In addition, Dr. Blackmon himself received three testosterone treatments at the Spa, without any prescription by another physician.

As to the fourth factor, the evidence established that Dr. Blackmon has worked as an orthopedic surgeon at the Orthopedic Center in Tulsa since 2003, he has been a partner in that surgical practice for several years, and the Orthopedic Center has about 120 employees. There was evidence that Dr. Blackmon timely paid \$62,000 in prior fines to state entities. Dr. Blackmon did not present any testimony or other evidence that his payment of those fines rendered him without assets or income to pay any additional fines. Similarly, while DX 3 indicates that five insurance companies informed Dr. Blackmon that he is no longer a participant in their provider networks, there was no testimony that those letters have impacted his ability to pay a fine.

The Court has reviewed the example cases cited in Dr. Blackmon's Trial Brief (Doc. 54), and concludes that those authorities do not indicate that the penalties imposed herein are inappropriate under the specific evidence presented in this case. By way of example, the court in *United States v. Paskon*, 4:07-CV-1161(CEJ), 2008 WL 4948458 (E.D. Mo. Nov. 10, 2008) (cited in defendant's Trial Brief, Doc. 54 at 6), imposed a \$1,000 penalty on each of seven violations, in part based upon evidence that the defendant owed \$823,000 to the Internal Revenue Service, had

assets that were heavily encumbered, and had retired from the practice of medicine. In contrast, Dr. Blackmon did not present any evidence that he has substantial debt or heavily encumbered assets, and he is still practicing medicine and is a partner in a successful orthopedic practice with 120 employees. Moreover, the physician in *Paskon* committed only seven violations, in contrast to Dr. Blackmon's 430 violations of the Act, and the *Paskon* court's imposition of a \$1,000 per violation penalty is *greater* than the penalties levied herein against Dr. Blackmon, with the exception of four of his 430 violations of the Act. Likewise, this Court has determined that Dr. Blackmon should pay a penalty of \$2500 for the failure to maintain a separate DEA registration in relation to his services at the Spa, which is *less* than the \$7500 penalty imposed in *United States v. Butterbaugh*, No. C14-515-TSZ, 2015 WL 4660096 (W.D. Wash. Aug. 5, 2015) for a failure to maintain a separate DEA registration.

IV. Summary

The Court finds and concludes that Dr. Blackmon committed 430 violations of the Act, for which he shall pay civil monetary penalties totaling \$296,000, consisting of: \$250 as to each of the 58 violations under Counts I through IV; \$750 as to each of the 368 violations under Count VI; \$1,000 as to each of the three violations under Count VII; and \$2,500 under Count VIII. Count V is dismissed with prejudice. A judgment will be entered forthwith.

SO ORDERED this 19th day of November, 2017.

JOHN E. DOWDELL UNITED STATES DISTRICT JUDGE